



U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT
850 THIRD AVENUE, BROOKLYN, NEW YORK 11232

D1110 B

Telephone: [718] 965-5300 [Ext 5301]

WARNING LETTER

CERTIFIED MAIL **RETURN RECEIPT REQUESTED**

Raymond D. Mutter, M.D.
President
Health Advantage, Inc.
777 North Broadway
North Tarrytown, New York 10591

January 17, 1997

Ref: 31-NYK-97

Dear Dr. Mutter:

This letter is written in reference to the marketing and distribution of "TPros" (formerly "Pros Care") Caplets by your firm.

Our review of the formulation and labeling, which includes promotional materials, for TPros finds the labeling suggests that the drug TPros is useful in treating and/or preventing benign prostatic hypertrophy and its symptoms. These claims include:

1. A brochure "Why suffer unnecessarily?" states: "Why suffer unnecessarily?...that irritating feeling of urgency...too frequent urination...slow flow and dribbling...sleepless or restless nights...loss of sexual desire...the embarrassment of occasional impotence"; "...suffering these upsetting symptoms of chronic inflammation and enlargement of the prostate gland,"; "Benign Prostatic Hypertrophy (BPH)"; "TPros is an exciting and unique compound of safe, natural ingredients that have been found to reduce the swelling of the prostate, relieve urinary discomfort and even POSTPONE the onset of BPH."; and "This unique combination of all-natural elements, Serenoa Repens, Pygeum Africanum, Zinc Picolinate, Vitamin B6 and Nettle Root Extract works to relieve the nagging symptoms of an enlarged prostate... ..as well as contribute to improved sexual performance."

2. A brochure "THE TPros REPORT Information about the treatment and prevention of prostate disorders" states: "POWERFUL NEW WEAPON AGAINST PROSTATE PROBLEMS DELIVERS SAFE, EFFECTIVE AND NATURAL RELIEF."; "TPros is a safe and effective compound that can help relieve enlarged prostate symptoms without resorting to expensive prescription drugs with unwanted side effects."; "...Serenoa Repens has also been thought to be an aphrodisiac."; "Pygeum helps ease prostate inflammation and has also been credited with contributing to improved sexual performance."; "...Zinc Picolinate and Vitamin B6 help combat the adverse effects of too much prolactin...it can contribute to the development of

tumors in the prostate."; and "The Nettle Root Extract inhibits the membrane activity of the prostate..."

3. A leaflet "In case you've decided to wait...here's some important advice from Dr. Mutter" states: "TPROS addresses the 3 most important issues for you: #1: Relief (and possible remission) from enlarged prostate problems. #2 Prevention of prostate difficulty in the first place. #3 Improved sexual performance."

4. An order form "TPros YOUR GUARANTEE OF SATISFACTION" states: "TPROS is a safe, effective formula containing a unique combination of all-natural ingredients designed to provide relief from the discomfort and distress of symptoms resulting from an enlarged and inflamed prostate."

In 1994, the Dietary Supplements Health and Education Act (DSHEA) was enacted, which defined dietary supplements and dietary ingredients; established a new framework for assuring safety; outlined guidelines for literature display; and provided guidance for literature displayed where supplements are sold. While DSHEA carefully describes the use of certain statements in the labeling of dietary supplements, these statements may not include claims for the diagnosis, prevention, mitigation, treatment, or cure of a specific disease. Products making disease claims are considered drugs, not dietary supplements.

Because the labeling includes statements which suggest that this product is intended for use in the cure, mitigation, treatment or prevention of disease, "TPros" is a drug [§ 201(g) of the Federal Food, Drug, and Cosmetic Act ("the Act")] and subject to the Final Monograph for OTC Benign Prostatic Hypertrophy drugs (Title 21, Code of Federal Regulations (CFR), Part 310.532). This regulation, which became effective on August 27, 1990, states that there are no active ingredients that are generally recognized as safe and effective for use as an OTC benign prostatic hypertrophy drug. TPros is a new drug [§ 201(p) of the Act], which may not be legally marketed in the United States unless a new drug application is approved for this drug.

The drug is misbranded [§ 502(a)] because its labeling is false and misleading and suggests that there is evidence that the drug is safe and effective for its intended uses when in fact this is not the case. The drug is further misbranded [§ 502(f)(1)] because its labeling fails to bear adequate directions for use.

This letter does not represent a comprehensive review of all the products your firm may market and distribute. It is your responsibility to ensure that all of your firm's products are in compliance with all requirements of the Act and its implementing regulations.

You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice. This action may include seizure and/or injunction.

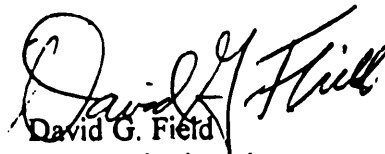
Health Advantage, Inc.

Page 3

Please notify this office in writing within 15 days of receipt of this letter, of the specific actions taken to correct the noted violations, including an explanation of each step being taken to prevent recurrence of similar violations. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply should be sent to Bruce A. Goldwitz, Compliance Officer, Food and Drug Administration, 850 Third Avenue, Brooklyn, New York 11232.

Sincerely,


David G. Field
Acting District Director

cc: John R. Pelletier, Secretary
Health Advantage, Inc.
560 White Plains Road
Tarrytown, New York 10591